

## **REMARKS**

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-11, 23, 24, 28 and 46-55 were pending in this application. Claims 23, 24, 28, 54 and 55 have been cancelled and claims 1 and 46 have been amended.

Claim 1 has been clarified to recite a veterinary parasitological spot-on formulation, which comprises: a) a veterinary parasitologically effective amount of an ectoparasitological combination consisting essentially of fipronil and amitraz; and b) a pharmaceutical or veterinary acceptable liquid carrier spot-on formulation vehicle for applying the formulation to a localized region on an animal wherein the localized region is less than 10 cm<sup>2</sup> and wherein the formulation optionally includes a crystallization inhibitor. Support may be found in the specification as originally filed, for example ¶¶ 9, 328 and 330 of the specification as published.

Claim 46 has been clarified to delete recitations to cancelled claims.

No new matter has been added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. THE 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTIONS ARE OVERCOME**

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Office Action, abbreviations should be spelled out at first appearance in claims. In response, claim 50 was amended to spell out the abbreviations, which are well known to one of skill in the art.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, second paragraph, are respectfully requested.

## II. THE 35 U.S.C. §103 REJECTIONS ARE OVERCOME

Claims 1-11, 23, 24, 28, and 46-57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over LAMM WO 03/015519 in view of HUET et al 64842425 and TENG- '93.

The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: "[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727. Furthermore, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, the references relied upon by the Office Action does not disclose, suggest or enable Applicants' invention. Applicants respectfully disagree with the characterization that there is no distinction between pour on and spot on in the claimed instant compositions. The recitation of spot on is in the preamble, which is a limitation of the instant claims; and, the surprising superiority of the instant invention is demonstrated in the present application.

In this regard, the Examiner is respectfully reminded that ALL words in the claims must be considered in evaluating the patentability of the claims over the prior art. *In re Wilson*, 165; see also *In re Swinehart*, 169 U.S.P.Q. 227 (C.C.P.A. 1971) ("point of novelty" was "transparen[cy]"; Court held that "functional" or "use" language was permissible, even at the "point of novelty" indicating that "there is nothing intrinsically wrong" with claiming by what

something does); *In re Duva*, 156 U.S.P.Q. 90 (C.C.P.A. 1967) (prior art rejection of aqueous solution "for depositing gold" reversed due to PTO failure to consider the "for depositing gold" recitation because "all factual differences which may be properly noted in any portion of a claim must be included within the basis for comparison with the prior art if we are to properly evaluate the difference between the invention defined in a claim and the teachings of a reference", i.e., "every portion of the ... claims must be considered"). For instance, it is well-established law that where the preamble is essential to point out the claimed invention and give meaning and vitality to the claim, it is given the effect of a limitation. See, e.g., *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671, F.2d 1359, 213 U.S.P.Q. 89 (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Walles et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); *Smith v. Bousquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940); *Ex parte Varga*, 189 U.S.P.Q. 204 (P.O.B.A. 1973); see also *Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951).

Initially, the cited references do not teach or suggest the combination of fipronil and amitraz especially in a spot-on formulation for localized application less than 10 cm<sup>2</sup>.

The Examiner is directed to the Examples of the specification which illustrate the unexpected effects of the present invention. The formulation according to the present invention remained effective for a far longer period of time than a formulation comprising fipronil alone. This enhanced efficacy is surprising since amitraz is not known in the art to be used in treating flea or tick infestations on mammals and birds. In fact, the Office Action admits that TENG relates to the use of amitraz in treating mites (not fleas or ticks).

Therefore, Applicants respectfully submit that nonobvious and unexpected results are derived from the invention as presently claimed.

According to Example 5, the fipronil/amitraz combination of the present invention remained effective for a far longer period of time than fipronil alone. For example, the fipronil/amitraz combination is over twice as effective at 58 days after treatment against ticks on dogs than fipronil alone.

According to Example 6, the fipronil/amitraz combination of the present invention exhibits a faster rate of efficacy than a formulation comprising fipronil alone. For example,

speed of efficacy of the fipronil/amitraz combination is 4 to 5 times as fast against ticks on dogs than fipronil alone 21 to 42 days after treatment.

According to Example 7, the fipronil/amitraz combination of the present invention remained effective for a far longer period of time than fipronil alone. For example, the fipronil/amitraz combination is over twice as effective at 51 days after treatment against fleas on dogs than fipronil alone.

As indicated above, the Examples in the specification demonstrate surprising superiority of the combination of fipronil and amitraz. In particular, there is no linear relationship when fipronil and amitraz are administered in combination as compared to fipronil alone. For example, as shown in Example 6, on Day 28, treatment with 10% of fipronil results in 21.3% efficacy against fleas. In comparison, on Day 28, treatment with 10% fipronil and 12% amitraz results in 95.2% efficacy against fleas. If there was a linear relationship between fipronil and amitraz, about 42% efficacy would have been expected. In contrast, there was a 95.2% efficacy—double the expected effect.

Therefore, contrary to the Office Action, Applicants have provided objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 103 are respectfully requested.